

Animal and Plant Health Inspection Service, USDA

§ 331.0

- 331.10 Restricting access to biological agents and toxins.
- 331.11 Biocontainment and security plan.
- 331.12 Training.
- 331.13 Transfer of biological agents and toxins.
- 331.14 Records.
- 331.15 Inspections.
- 331.16 Notification in the event of theft, loss, or release of a biological agent or toxin.
- 331.17 Administrative review.

AUTHORITY: Secs. 211–213, Title II, Pub. L. 107–188, 116 Stat. 647 (7 U.S.C. 8401).

SOURCE: 67 FR 76925, Dec. 13, 2002, unless otherwise noted.

§ 331.0 Effective and applicability dates.

(a) The regulations in this part are effective on February 11, 2003. On and after that date, any person possessing, using, or transferring any agent or toxin listed in § 331.3 must be in compliance with the provisions of this part. However, so as not to disrupt research or educational projects involving listed agents or toxins that were underway as of the effective date of this part, any person possessing such agents or toxins as of the effective date (current possessors) will be afforded additional time to reach full compliance with this part. Any provision not specifically cited in paragraphs (a)(1) through (a)(6) of this section will be applicable as of February 11, 2003. In addition, any individual or entity who does not possess listed agents or toxins by the effective date of this part, but who wishes to initiate a research or educational project prior to November 12, 2003, must be in compliance with the provisions of this part that are applicable for current possessors at the time of application, as provided in paragraphs (a)(1) through (a)(5) of this section.

(1) During the period from February 11, 2003, to November 12, 2003, biological agents or toxins listed in § 331.3 may only be transferred to an individual or entity that is not registered under this part if the individual or entity has been issued a permit by the Administrator under part 330 of this chapter to import or move interstate that specific agent or toxin. If an individual or entity has not been issued a permit under part 330 of this chapter, the individual or entity may apply for a permit. To

receive an agent or toxin, an individual or entity will also be required to submit APHIS Form 2041, in accordance with § 331.13(c). Because USDA permits do not cover intrastate movement, an individual or entity may not receive a listed agent or toxin that is being moved intrastate until that individual or entity is registered in accordance with this part.

(2) By March 12, 2003, the responsible official must submit the registration application package as required in § 331.8. In addition, the responsible official must submit to the Attorney General the names and identifying information for the responsible official; alternate responsible official, where applicable; entity; and, where applicable, the individual who owns or controls the entity.

(3) By April 11, 2003, the responsible official must submit to the Attorney General the names and identifying information for all individuals whom the responsible official has identified as having a legitimate need to handle or use listed agents or toxins, and who have the appropriate training and skills to handle such agents or toxins, as required in § 331.10.

(4) By June 12, 2003, the responsible official must submit to APHIS the security section of the Biocontainment and Security Plan required in § 331.11.

(5) By September 12, 2003, the responsible official must implement the security section of the Biocontainment and Security Plan, as required in § 331.11, and provide security training in accordance with 7 CFR 331.12.

(6) By November 12, 2003, the registration application process must be complete and the entity in full compliance with the regulations in this part, except as otherwise provided in paragraphs (b) and (c) of this section.

(b) *Provisional registration.* (1) Notwithstanding the provisions in paragraph (a) of this section, APHIS may issue a provisional registration certificate to current possessors if, as of November 12, 2003:

(i) The Attorney General has received all of the information, including fingerprint cards, required by the Attorney General to conduct a security risk assessment of the entity, including any

individual who owns or controls the entity; and

(ii) The entity otherwise meets all of the requirements of this part.

(2) Notwithstanding the provisions in paragraph (a) of this section, APHIS may issue a provisional registration certificate to individuals and entities that did not possess listed biological agents or toxins as of February 11, 2003, if, as of November 12, 2003:

(i) The Attorney General has received all of the information, including fingerprint cards, required by the Attorney General to conduct a security risk assessment of the entity, including any individual who owns or controls the entity;

(ii) The entity otherwise meets all of the requirements of this part; and

(iii) The Administrator finds that circumstances warrant such action in the interest of the health of plants or plant products or national security.

(3) A provisional registration certificate will be effective until APHIS either issues a certificate of registration or suspends or revokes the provisional registration.

(c) Notwithstanding the provisions in paragraph (a) of this section, APHIS may issue a provisional grant of access for individuals identified by an entity as having a legitimate need to handle or use agents or toxins listed in § 331.3 if, as of November 12, 2003, the Attorney General has received all of the information, including fingerprint cards, required by the Attorney General to conduct a security risk assessment of that individual. A provisional grant of access will be effective until APHIS grants or denies access to biological agents or toxins listed in § 331.3.

[68 FR 62220, Nov. 3, 2003]

§ 331.1 Definitions.

Administrator. The Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the Administrator.

Animal and Plant Health Inspection Service (APHIS). The Animal and Plant Health Inspection Service of the United States Department of Agriculture.

Attorney General. The Attorney General of the United States or any person authorized to act for the Attorney General.

Biological agent. Any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing:

(1) Death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism;

(2) Deterioration of food, water, equipment, supplies, or material of any kind; or

(3) Deleterious alteration of the environment.

Centers for Disease Control and Prevention (CDC). The Centers for Disease Control and Prevention of the United States Department of Health and Human Services.

Diagnostic laboratory. A laboratory facility that receives specimens for the purpose of determining the identities of pests, pathogens, contaminants, or causes of disease.

Entity. Any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.

Import. To move into, or the act of movement into, the territorial limits of the United States.

Interstate. From one State into or through any other State, or within the District of Columbia, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.

Permit. A written authorization by the Administrator to import or move interstate biological agents or toxins, under conditions prescribed by the Administrator.

PPQ. The Plant Protection and Quarantine Programs of the Animal and Plant Health Inspection Service

Responsible official. The individual designated by an entity to act on its behalf. This individual must have the authority and control to ensure compliance with the regulations in this part.

Specimen. A sample of material collected for use in testing, such as plant tissues (e.g., stems, seeds, flowers, pollen, leaves, roots, fruits, tubers, tissue